CERTIFIED MAIL

Mr. Brent Solomon
Valent USA Corp.
1401 Eye Street, N.W.
Suite 220
Washington, DC 20005

SUBJECT: NALED: Review of an Acute Dietary Exposure Analysis and Risk Assessment for Naled Residues in Foods, MRID number 44485101.

Dear Mr. Solomon:

The Agency has reviewed the acute dietary exposure assessment provided by Valent in support of the reregistration of Naled. The Agency has determined that the Monte Carlo assessment, as submitted, is unacceptable for regulatory purposes. The results of the review, conducted by the Health Effects Division, are attached for your use.

If you have any questions or comments, please contact Diane Isbell at (703) 308-8154.

Sincerely,

Kathy S. Monk, Chief
Reregistration Branch II
Special Review and
Reregistration Division (7508W)

Enclosure

cc: M. Rust, HED

May 6, 1998

MEMORANDUM

SUBJECT: Naled (034401) Reregistration Case No. 0092
Monte Carlo Assessment submitted by Registrant

[MRID No. 44485101; DP Barcode: D245589]

FROM: Susan V. Hummel, Chemist/Branch Senior Scientist
Chemistry and Exposure Branch 2
Health Effects Division [7509C]

THRU: Francis B. Suhre, Chemist/Branch Senior Scientist
Chemistry and Exposure Branch 1
Health Effects Division [7509C]

TO: Brian Steinwand
Chemistry and Exposure Branch 1
Health Effects Division [7509C]

Valent U. S. A. Corporation has submitted a probabilistic (Monte Carlo) dietary exposure and risk assessment for residues of naled on foods. The assessment was performed by Novigen Sciences, Inc., using their Dietary Exposure Evaluation Model (DEEM) software. Summaries of the data used in the assessment were provided in one paragraph of text per crop and tables summarizing the data. A brief review of the Monte Carlo assessment was requested.

Tolerances are established for combined residues of naled (1,2-dibromo-2,2-dichloroethyl dimethyl phosphate) and its conversion product 2,2-dichlorovinyl dimethyl phosphate (dichlorvos or DDVP), calculated as naled equivalents [40 CFR §180.215], on numerous crops resulting from agricultural use. Additionally, tolerances are established for all raw agricultural commodities to cover residues resulting from naled wide area mosquito and fly use. There are no established food or feed additive tolerances for naled.

Conclusions and Recommendations

The available field trial data on naled are too limited to be of use in a probabilistic dietary exposure assessment. Unless the registrant can demonstrate that there are sufficient, geographically representative residue data at the registered application rate and PHI (or the typical rate and PHI), a point estimate should be used. Use of processing factors is appropriate, although the choice of cooking times should be justified by consumer practice data or standard cookbook recipes for that particular commodity.

General Comments

1. The assessment was based on field trial data for naled and dichlorvos, calculated as naled. Data from some processsing and cooking studies were included, although it was not clear how this information was incorporated into the dietary exposure assessment.

2. Residues from the wide area treatment were excluded from the probabilistic acute dietary exposure analysis. Novigen noted that the percent of crop treated from the mosquito use was less than 1%, and that EPA guidance recommended excluding this use from the acute dietary exposure analysis. Presumably they assumed that this wide area treatment would be analogous to food handling establishment uses. We note that the application rate for the wide area treatment is substantially lower than the application rate for agricultural uses. No comment will be made on this assumption at this time. We note that people in some areas of the country would be exposed to residues from this use much more than people in other areas of the country.

3. Residues in meat, milk, poultry, and eggs could result from secondary residues of naled in livestock feeds. Dermal uses on poultry have been voluntarily canceled. There are no dermal uses on other livestock. Livestock feeds which could have naled residues include almond hulls, cottonseed, cotton gin trash, orange pulp, safflower seed, sugar beet tops, and sugar beet pulp. Novigen constructed a realistic, nutritionally balanced diet from these feeds, and included untreated corn and soy feeds for the balance of the diet.

4. The submission is fairly good in summarizing all available field trial data, and all available processing and special processing studies. However, the data which were summarized are insufficient on which to base a Monte Carlo Assessment. For most crops, there is only one field trial location selected by the registrant to be included. There is insufficient geographic representation, and insufficient data at the use pattern on the label. If the field trial data are not adequate to support the current (or proposed) registration, then the data are insufficient to support a Monte Carlo Assessment.

5. With regard to the processing studies and special processing studies, there was no justification of the processing factors which were chosen for the monte carlo assessment. For celery, there are special processing studies reflecting a number of cooking conditions. For example, for celery, I

believe that there were cooking data for boiling 2 minutes, 20 minutes, and 30 minutes. There was no authoritative evidence of the conditions normally used for cooking celery. Similar things can be said for the other processing studies. Without this discussion of how the appropriate factors were chosen and that choice justified, the Monte Carlo analysis is not supported.

cc: RF, Naled SF, M. Clock (RCAB)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of an Acute Dietary Exposure Analysis and Risk Assessment for Naled Residues in Foods (Valent Report MRID No.44485101) submitted in support of the reregistration of Naled

FROM: Brian Steinwand
Chemistry Exposure Branch 1
HED (7509C)

Through: Elizabeth Doyle, Chief
Chemistry Exposure Branch 1
Health Effects Division

E. a. Doyle

TO: S. Knizner
RCAB (7509C)

Action Requested

Review a probabilistic (Monte Carlo) dietary exposure and risk assessment for residues of Naled on foods submitted by Valent U.S.A. Corporation.

Results

The acute dietary exposure assessment provided by Valent Corporation in support of the reregistration of Naled was found to be unacceptable for regulatory purposes (See memo, S. Hummel, 5/6/98). A review of the submission shows that there are insufficient data on which to base a Monte Carlo assessment. For most crops, there is only one field trial location selected by the registrant to be included in the assessment. By looking at the data summaries, it appears that there is insufficient geographical representation, and insufficient data on use patterns on the label to be of use in a probabalistic exposure assessment.

As for the processing studies and special processing studies, there was no discussion of how the appropriate factors (i.e. cooking times) were chosen. Without a justification of what factors were included in the Monte Carlo analysis, the analysis can not be supported. However, if the factors such as cooking times were taken from studies previously submitted to the Agency, the registrant should resubmit them for review.

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